

REMARKS

Reconsideration is respectfully requested.

The Examiner's rejections will be considered in the order of their occurrence in the Office Action.

Part 1 of the Office Action

Claim 12 has been rejected under 35 U.S.C. §112 (second paragraph) as being indefinite.

The above amendments to claim 12 are believed to clarify the requirements of the rejected claims, especially the particular points identified in the Office Action.

Withdrawal of the §112 rejection of claim 12 is therefore respectfully requested.

Parts 2 through 6 of the Office Action

Claims 1 through 6 have been rejected under 35 U.S.C. §102(b) as being anticipated by Miller et al. (US 5,579,774).

Claims 7 through 9 have been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Miller et al (US 5,579,774 A) in view of Knute et al. (US 4,903,707 A).

Claim 10 has been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Miller et al (US 5,579,774 A) in view of Lake (US 3,766,910 A).

Claim 11 has been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Miller et al (US 5,579,774 A) in view of Baudino (US 6,110,155 A).

Claim 12 has been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Miller et al (US 5,579,774 A) in view of Baudino (US 6,110,155 A), as applied to claim 11 above, further in view of McNeil et al (US 4,828,546 A).

Claims 1 and 6, particularly as amended, require "retaining

means on the exterior surface of the tubular portion adjacent to the distal end for engaging an interior surface of a conduit with a flexible wall to releasably retain the conduit on the distal end of the tubular portion".

The Miller reference cited in the Office Action discloses an "apparatus for monitoring local cerebral physiology". The Miller apparatus appears to be primarily directed to a probe 40 that extends through a subarachnoid bolt 11. The bolt 11 has a non-penetrating end with an exterior surface that is clearly threaded for being received in and threadedly engaging a cap 13. See, for example, Miller at col. 8, lines 43 through 55 (emphasis added):

The subarachnoid bolt 11 is a disposable skull mounting device having a lumen or passage with openings which provide intracranial access when it screwed into the cranium. When the combined probe 40 passes through the elements of the intracranial access system 20 and the locking cap 13 is securely screwed onto the subarachnoid bolt 11, the constricting ring 15, which includes a bore, and the O-ring 17 cooperate to secure the probe and provide an airtight seal around the probe for intracranial sterility and stability, as well as to prevent the introduction of light artifact within the locus of measurement. Such a coupling member is analogous to what is sometimes referred to as a compression fitting.

It is submitted that one of ordinary skill in the art, considering the exterior threads formed on the end of the bolt 11 of Miller, would not be led to the applicant's requirement of "retaining means on the exterior surface of the tubular portion adjacent to the distal end for engaging an interior surface of a conduit with a flexible wall to releasably retain the conduit on the distal end of the tubular portion" in claim 1. It is submitted that one of ordinary skill in the art would never consider the threads formed on the end of the bolt 11 of Miller as being suitable or workable for engaging and retaining a conduit with a flexible wall on an exterior surface of

a bolt or other structure.

Further, claims 4 and 5 each require "wherein the retaining means comprises a plurality of annular barbs formed on the exterior surface adjacent the distal end of the tubular portion". It is submitted that one of ordinary skill in the art, considering the threads of Miller forming its "compression fitting" structure, would never be led to the claimed annular barbs, which would be incapable of engaging the locking cap 13 of Miller to form the compression fitting relationship.

The Knute et al. reference teaches a catheter assembly that has a "bolt means 17" that is similar to the teaching of the Miller reference, and also has threads 47 formed on the second extremity 27 of the bolt means 17 for engaging a "threaded cap 45". It is submitted that the Knute et al. reference would not lead one of ordinary skill in the art closer to the requirements of claim 1 than the Miller reference, especially considering the retaining means requirement of claim 1.

Further, the Lake, Baudino, and MacNeil references are submitted to lack any suggestion of the claimed retaining means in combination with the other claimed features of the invention.

It is therefore submitted that the prior art, and especially the allegedly obvious combination of Miller et al., Knute et al., Lake, Baudino, and MacNeil et al. patents set forth in the rejection of the Office Action, would not lead one skilled in the art to the applicant's invention as required by claims 1 and 6. Further, claims 2 through 5, which depend from claim 1, and claims 7 through 12, which depend from claim 6, also include the requirements discussed above and therefore are also submitted to be in condition for

allowance.

Withdrawal of the §102(b) and §103(a) rejections of claims 1 through 12 is therefore respectfully requested.

Added Claims 33 through 41

Claims 33 and 37 each require "wherein the retaining means facilitates sliding insertion of the distal end of the tubular portion into the conduit and resists sliding removal of the conduit from the distal end of the tubular member". It is submitted that the threads of the Miller et al. and Knute et al. references do not perform such as function and would not lead one of ordinary skill in the art to such a function.

Claims 38 and 40 each require "wherein the retaining means comprises a plurality of annular barbs formed on the exterior surface of the tubular portion", and claims 34, 36, 40, and 41 each require "wherein the retaining means comprises at least three annular barbs formed on the exterior surface of the tubular portion adjacent to the distal end". It is submitted that the threads of the Miller et al. and Knute et al. references do not show, nor do they suggest, the claimed annular barbs of these claims.

Claims 35, 36, 39 and 40 each require "wherein each of the annular barbs comprises a frustaconical surface for facilitating sliding insertion of the distal end of the tubular portion into the conduit and an adjoining annular shoulder surface that resists sliding removal of the conduit from the distal end of the tubular member". Again, it is submitted that the threads formed on the exterior of the Miller et al. and Knute et al. references would not lead one of ordinary skill in the art to the barbs with a frustaconical surface and a annular shoulder.

VERSION WITH MARKINGS TO SHOW CHANGES MADE:

In the Claims (bracketed parts deleted and underline parts added):

1. (Amended) A subdural evacuating port device for evacuating a collection of fluid from a subdural space of a patient, comprising:

a tubular portion for partial insertion into an opening in a skull of a patient, the tubular portion having a proximal end and a distal end and a lumen extending between the proximal and distal ends, the tubular portion having an exterior surface; [and]

a pair of wings for facilitating finger rotation of the tubular portion, the wings extending outwardly from the tubular portion in substantially opposite directions from the tubular portion; and

retaining means on the exterior surface of the tubular portion adjacent to the distal end for engaging an interior surface of a conduit with a flexible wall to releasably retain the conduit on the distal end of the tubular portion.

2. (Pending) The subdural evacuating port device of claim 1 wherein the wings are mounted on the tubular portion at a location medial between the proximal and distal ends of the tubular portion.

3. (Pending) The subdural evacuating port device of claim 1 wherein the exterior surface at the proximal end of the tubular portion has self-tapping threads formed thereon adapted for cutting threads into the opening in the skull of a patient.

4. (Amended) The subdural evacuating port device of claim 1 wherein the [exterior surface at the distal end of the tubular portion has] retaining means comprises a plurality of annular barbs formed [thereon for retaining an end of a conduit thereon] on the exterior surface adjacent the distal end of the tubular portion.

5. (Amended) The subdural evacuating port device of claim 1 wherein the wings are mounted on the tubular portion at a location medial between the proximal and distal ends of the tubular portion, wherein the exterior surface at the proximal end of the tubular portion has self-tapping threads formed thereon adapted for cutting threads into an opening in a skull of a patient, and wherein the [exterior surface at the distal end of the tubular portion has] retaining means comprises a plurality of annular barbs formed [thereon for retaining an end of a conduit thereon] on the exterior surface adjacent the distal end of the tubular portion.

6. (Amended) A kit for evacuating a collection of fluid from a subdural space of a patient having a scalp, comprising:
a subdural evacuating port device having a proximal end and a distal end, the subdural evacuating port device having a tubular portion with a lumen extending between the proximal and distal ends, an exterior surface of the proximal end of the tubular portion having self-tapping threads formed thereon for cutting threads into a skull, [an exterior surface of the distal end of the tubular portion having a plurality of annular barbs formed thereon for retaining a flexible hose] retaining means on the exterior surface of the tubular portion adjacent to the distal end for engaging an interior surface of a conduit with a flexible wall to releasably retain the conduit on the distal end of the tubular portion, and a pair of wings extending outwardly from the tubular portion, the wings extending in opposite directions.

7. (Pending) The kit of claim 6 additionally comprising a drill bit for forming an opening in the skull of the patient.

8. (Pending) The kit of claim 7 additionally comprising a stop collar selectively lockable in a position on the drill bit for setting the maximum penetration of the drill bit into a surface.

9. (Pending) The kit of claim 6 additionally comprising a conduit having first and second ends, the first end being adapted for connection to the subdural evacuating port device, the second end of the conduit being for connection to a negative pressure source.

10. (Pending) The kit of claim 6 additionally comprising a retractor for spacing sides of an incision in a scalp away from each other, the retractor comprising a pair of arms each having a proximal ends joined together to form an apex, each of the arms extending away from the apex such that distal ends of the arms are spaced from each other, the arms of the retractor forming a substantially V-shaped configuration.

11. (Pending) The kit of claim 6 additionally comprising a negative pressure device for creating a negative pressure condition.

12. (Amended) The kit of claim 11 wherein the negative pressure device comprises a [Jackson-Pratt] suction bulb having a pair of openings, the [Jackson-Pratt] bulb having an interior, the bulb having a primary opening and a secondary opening between the interior and an exterior of the bulb, a check valve in communication with the primary opening for resisting exit of fluid from the interior of the bulb to the exterior of the bulb through the primary opening and permitting fluid flow into the interior through the primary opening, a cap for selectively closing the secondary opening of the [Jackson-Pratt] bulb.

Claims 13 through 32 have been withdrawn without prejudice as being drawn to a non-elected embodiment.

Please add the following claims:

33. (Added) The subdural evacuating port device of claim 1 wherein the retaining means facilitates sliding insertion of the distal end of the tubular portion into the conduit and resists sliding removal of the conduit from the distal end of the tubular member.

34. (Added) The subdural evacuating port device of claim 1 wherein the retaining means comprises at least three annular barbs formed on the exterior surface of the tubular portion adjacent to the distal end.

35. (Added) The subdural evacuating port device of claim 4 wherein each of the annular barbs comprises a frustaconical surface for facilitating sliding insertion of the distal end of the tubular portion into the conduit and an adjoining annular shoulder surface that resists sliding removal of the conduit from the distal end of the tubular member.

36. (Added) The subdural evacuating port device of claim 1 wherein the retaining means comprises at least three annular barbs formed on the exterior surface of the tubular portion adjacent to the distal end; and

wherein each of the annular barbs comprises a frustaconical surface for facilitating sliding insertion of the distal end of the tubular portion into the conduit and an adjoining annular shoulder surface that resists sliding removal of the conduit from the distal end of the tubular member.

37. (Added) The kit of claim 6 wherein the retaining means facilitates sliding insertion of the distal end of the tubular portion into the conduit and resists sliding removal of the conduit from the

distal end of the tubular member.

38. (Added) The kit of claim 6 wherein the retaining means comprises a plurality of annular barbs formed on the exterior surface of the tubular portion.

39. (Added) The kit of claim 38 wherein each of the annular barbs comprises a frustaconical surface for facilitating sliding insertion of the distal end of the tubular portion into the conduit and an adjoining annular shoulder surface that resists sliding removal of the conduit from the distal end of the tubular member.

40. (Added) The kit of claim 6 wherein the retaining means comprises at least three annular barbs formed on the exterior surface of the tubular portion adjacent to the distal end.

41. (Added) The kit of claim 6 wherein the retaining means comprises a plurality of annular barbs formed on the exterior surface of the tubular portion;

wherein each of the annular barbs comprises a frustaconical surface for facilitating sliding insertion of the distal end of the tubular portion into the conduit and an adjoining annular shoulder surface that resists sliding removal of the conduit from the distal end of the tubular member; and


wherein the plurality of annular barbs includes at least three of the annular barbs formed on the exterior surface of the tubular portion adjacent to the distal end.

CONCLUSION

In light of the foregoing amendments and remarks, early reconsideration and allowance of this application are most courteously solicited.

Respectfully submitted,

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